

REMARKS

Claims 1 – 22 are pending in this application.

Claims 1 – 22 have been rejected.

Claims 13 and 22 have been objected to.

Claims 13 and 21 have been amended.

Amendments to the Claims

Applicant acknowledges the renumbering of claims 5 – 23 as claims 4 – 22 and appreciates the corrections. The claims will henceforth be referred to as renumbered by the Examiner.

Claims 6 – 10, 13 and 15 have been amended to maintain consistency with the originally filed dependencies. No new matter has been added.

Claim 13 has been amended to clarify that the mold is accomplished “in situ”, not “in an in situ mold”. This change was made to rectify an informality objected to by the Examiner. No new matter has been added.

Claim 21 has been amended to clarify that it is not a “means for recharging coil” that is being attached, but rather “means for recharging” that is being attached. This change corrects a typographical error that caused the recharging means element to be referenced as a recharging coil. No new matter has been added.

Claim Objections

The Examiner’s renumbering of claims 5 – 23 as claims 4 – 22, and the dependency amendments made to claims 6 – 10, 13 and 15 herein, have cured the Examiner’s objections to the misnumbering of claims 5 – 23.

Claim 13 has been objected to because of an informality. The requested clarification changing “accomplished in an in situ mold” to “accomplished in situ” has been made. With this amendment, the Examiner’s objection to claim 13 should now be cured.

Claim 22 [sic, actually claim 21 as renumbered by the Examiner] has been objected to due to lack of antecedent basis for the phrase “means for recharging coil.” Claim 21 has been amended to instead refer to “means for recharging” which has proper antecedent basis in claim 21 at line 9. With this amendment, the Examiner’s objection to claim 21 should now be cured.

Double Patenting

Claims 1, 2, 7, 8, 18, 19 and 20 – 22 have been rejected on the ground of nonstatutory, obviousness-type double patenting as being unpatentable over claims 1, 12 – 15 and 19 – 20 of U.S. Patent No. 6,505,077 B1.

Submitted herewith is a terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) disclaiming any remaining term in a patent issuing from the above-identified application which extends beyond the remaining term of U.S. Patent No. 6,505,077, if any; and a patent issuing from the above-identified application shall be enforceable only for and during such period that said patent is commonly owned with U.S. Patent No. 6,505,077 or any patent issuing therefrom. Such terminal disclaimer is timely filed and signed in accordance with the provisions of 37 CFR 1.321(b)(1)(iv) by the attorney of record.

The terminal disclaimer submitted should cure the rejections of claims 1, 2, 7, 8, 18, 19 and 20 – 22 for nonstatutory, obviousness-type double patenting and such rejections should be withdrawn.

Rejections under 35 U.S.C. § 112 6th Paragraph

Claim 21 has been objected to under 35 USC § 112, sixth paragraph, for failing the three prong test. With the amendment of claim 21, the objection of claim 21 under 35 USC § 112, sixth paragraph, it is respectfully submitted that the objection has been cured.

The Examiner states that inclusion of the word “coil” disqualifies the claim from proper obtaining 35 USC § 112, sixth paragraph, protection. The amendment made to

claim 21 deletes the objectionable word “coil” and, thus, should cure the Examiner’s objection.

Rejections under 35 U.S.C. § 112 2nd Paragraph

Claim 21 has been rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. This rejection is respectfully traversed.

As the Examiner noted, the specification describes attaching by “encapsulation with polymer” or by “overmolding with a polymer” (page 7, lines 28 – 30). In addition, the specification describes other methods of attachment such as “latches, barbs, polymer anchors, and the like” (page 5, lines 12 – 13). 35 U.S.C. §112 6th paragraph states that means claims “shall be construed to cover the corresponding structure, material or acts described in the specification and equivalents thereof.” MPEP § 2181.II states that the applicant “must set forth in the specification an adequate disclosure showing what is meant by that language” (citing *In re Donaldson Co.*, 16 F.3d 1189 (Fed. Cir. 1994)). The corresponding structure “must be disclosed in the specification itself in a way that one skilled in the art will understand what structure will perform the recited function.”

Thus, it is clear that the attachment means referred to in the claim include all of the attachment means described in the specification, and reasonable equivalents thereof. The recitation of “encapsulation with polymer,” “overmolding with polymer,” and “latches, barbs, polymer anchors, and the like” are more than sufficient to describe to one skilled in the art various attachment means that “will perform the recited function.” The Applicant is seeking section 112, paragraph six, protection for all of the aforementioned structures, as well as any other structure identified in the specification as a means for attachment, as well as all reasonable equivalents of any of the structures recited in the specification.

The Applicant cannot identify any language in the MPEP that says the Applicant may not recite a plurality of adequately described and suitable structures to which a means-plus claim may refer. Thus, it is respectfully submitted that the rejection of claim

21 under 35 U.S.C. §112 for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention is improper and should be withdrawn.

Rejections under 35 U.S.C. § 102

Rejections in view of Leysieffer '677

Claims 1-3, 5-7, 11-13, 17 and 19-21 have been rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,154,677 ("Leysieffer '677"). These rejections are respectfully traversed.

Leysieffer '677 discloses a recharging coil that can be attached to the housing of an implantable device, as well as a rechargeable battery and electronics carried within the implantable device (column 5, lines 21 – 39). However, Leysieffer '677 does not show, disclose or suggest that the recharging coil is centrally located – as depicted in Figures 1 – 6, the recharging coil (106) is positioned not at the center of the device, but rather the coil is, in each case, distinctly well away from the center of the implantable device.

By contrast, claims 1 and 21 specifically require "a recharging coil centrally located" (claim 1, line 9; similar language in claim 21, line 14). The centrally located recharging coil is aptly illustrated in Figures 2 and 5 – 8 of the present invention, and the difference compared with the positioning of the recharging coil in Leysieffer '677 is significant. An implanted medical device typically is implanted at a depth such that a bulge of some size is detectable from either visual or tactile inspection. The visual or tactile identification of the location of the implanted medical device is significant for charging or recharging or otherwise servicing or communicating with the implanted medical device. With a visual or tactile representation of the location of the implanted medical device, it is natural and understandable that a user would use such visual or tactile identification as an identification to the position to location an external device, such as an external recharging coil, to recharge or otherwise communicate with the implanted device. Without the recharging coil being centrally located, the user may be misled as to the proper location with which to position an external device and may very

well achieve inferior performance due to an inaccurate positioning of the external device with respect to the recharging coil directly due to the lack of central location.

Claims 1 and 21 require a structure that is simply not shown, disclosed or suggested by Leysieffer '677, which depicts a coil located not centrally, but rather off to the side of the device.

Leysieffer '677 does not show, disclose or suggest a centrally located recharging coil, and instead teaches away from a centrally located recharging coil by only depicting the coil positioned well separated from the center of the implantable device. Thus, it is respectfully submitted that the rejection of claims 1 and 21 under 35 U.S.C. § 102(b) in view of Leysieffer '677 is improper and should be withdrawn.

Claims 2, 3, 5 – 7, 11 – 13, 17, 19 and 20 are dependent on claim 1, and thus incorporate all of the limitations of claim 1. Because the rejection of claim 1 is improper, it is respectfully submitted that the rejections of claims 2, 3, 5 – 7, 11 – 13, 17, 19 and 20 are also improper and should be withdrawn.

Rejections in view of Fagan '129

Claims 1, 5 and 9 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 3,824,129, ("Fagan '129"). These rejections are respectfully traversed.

As noted by the Examiner, Fagan '129 discloses a recharging coil operatively connected to an electric cell which is connected via a control circuit to a pacemaker (column 7, line 64 – column 8, line 16). However, Fagan '129 does not show, disclose or suggest that the battery cell is contained within the housing of the pacemaker; as depicted in Figures 1 and 2, pacemaker 24 is physically separated from battery cell 20, and battery cell 20 is not depicted in any internal view of the pacemaker (Figures 5 and 7). In addition, Fagan '129 does not show, disclose or suggest that the recharging coil is centrally located.

By contrast, claim 1 specifically requires "a recharging coil centrally located" (claim 1, line 9) and "a rechargeable power source carried in the housing interior cavity"

(claim 1, line 7). Fagan '129 simply does not show, disclose or suggest the structure required by claim 1; the recharging coil is not "centrally located", and the battery is not depicted as being carried in a housing interior cavity. Instead, Fagan '129 seems to suggest carrying the recharging coil and battery in a separate module distinct and away from the pacemaker, in contrast to the requirements of claim 1, which require the battery to be located within the implantable medical device.

Thus, it is respectfully submitted that the rejection of claim 1 under 35 U.S.C. § 102(b) in view of Fagan '129 is improper and should be withdrawn.

Claims 5 and 9 depend on claim 1, and thus are subject to all of the limitations of claim 1. Because the rejection of claim 1 is improper, it is respectfully submitted that the rejection of claims 5 and 9 are also improper and should be withdrawn.

Rejections in view of Fischell '260

Claims 1, 5, 8, 11, 17 and 19 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 3,888,260, ("Fischell '260") as disclosed by the Applicant. These rejections are respectfully traversed.

Fischell '260 discloses an implantable medical device which includes, within an outer casing, an "input transformer", a rechargeable battery operatively connected to the input transformer, and electronics contained within an "inner can" (column 4, line 36 – column 5, line 31). Thus, as clearly depicted in Figures 2 and 3, the input transformer is contained within the same casing as the rechargeable battery and electronics. As a result, Fischell '260 does not show, disclose or suggest recharging coil electrically coupled through a housing electrical feedthrough to the electronics and rechargeable power source; in other words, the recharging coil must be outside of the housing in order for there to be a feedthrough to the rechargeable power source.

By contrast, claim 1 of the present invention requires a recharging coil "electrically coupled through the housing electrical feedthrough to the electronics and rechargeable power source" (claim 1, lines 10 – 11). By contrast, Fischell '260 does not show, disclose or suggest an external recharging coil electrically coupled through the

housing via a feedthrough. In fact, Fischell '260 has no need whatsoever for a feedthrough, because, as depicted by Figures 2 and 3, the recharging coil and rechargeable battery are located within the same cavity in the interior of the implantable medical device.

Fischell '260 does not show, disclose or suggest connecting a charging coil external to the implantable medical device to a rechargeable battery using a feedthrough. Thus, it is respectfully submitted that the rejection of claim 1 under 35 U.S.C. § 102(b) in view of Fischell '260 is improper and should be withdrawn.

Claims 5, 8, 11, 17 and 19 are dependent on claim 1, and thus are subject to all of the limitations of claim 1. Because the rejection of claim 1 is improper, it is respectfully submitted that the rejection of claims 5, 8, 11, 17 and 19 are also improper, and should be withdrawn.

Rejections in view of Baumann et al '292

Claims 1, 16 and 18 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,279,292, ("Baumann et al. '292"). These rejections are respectfully traversed.

Baumann et al '292 discloses an implantable medical device with a recharging coil, a rechargeable power source, and electronics, all contained within the housing of the implantable medical device (column 3, lines 4 – 33). However, Baumann et al '292 does not show, disclose or suggest a recharging coil connected to a rechargeable battery and electronics via a feedthrough. In addition, Baumann et al '292 does not show, disclose or suggest a coil that is centrally located.

By contrast, claim 1 a recharging coil "electrically coupled through the housing electrical feedthrough to the electronics and rechargeable power source" (claim 1, lines 10 – 11), and that the recharging coil be "centrally located " (claim 1, line 9). Baumann et al '292 simply does not show, disclose or suggest the recharging coil being carried external to the rest of the components of the implantable medical device, such that a feedthrough would be required; the coil is depicted as being carried inside the housing of

the implantable medical device (Figures 1, 2 and 4). Furthermore, Baumann et al '292 does not show, disclose or suggest that the recharging coil is centrally located; in fact, Baumann et al '292 does not depict a view of the implantable medical device other than a block diagram, and thus does not show, disclose or suggest a location for the coil at all.

Baumann et al '292 does not show, disclose or suggest a recharging coil connected to a rechargeable battery and to electronics via a feedthrough, nor that the recharging coil be centrally located. Thus, it is respectfully submitted that the rejection of claim 1 under 35 U.S.C. § 102(b) in view of Baumann et al '292 is improper and should be withdrawn.

Claims 16 and 18 are dependent on claim 1, and thus are subject to all of the limitations of claim 1. Because the rejection of claim 1 is improper and should be withdrawn, it is respectfully submitted that the rejection of claims 16 and 18 is also improper and should be withdrawn.

Rejections in view of Susset et al '477

Claims 1-7, 9, 14, 16 and 20-22 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 3,667,477, ("Susset et al. '477"). These rejections are respectfully traversed.

Susset et al '477 discloses an implantable medical device with a coil connected to the implantable medical device via feedthrough wires. However, Susset et al '477 does not show, disclose or suggest a rechargeable power source. In fact, Susset et al '477 specifically states that it "requires no free charging of an internal power supply" (abstract, and throughout the specification); i.e., there is no internal power supply. The mere existence of a capacitor in a circuit does not, in and of itself, create a "rechargeable power source" in the way that any person of ordinary skill in the art would recognize as a "power source"; by specifically disclaiming the existence of an internal power source, Susset et al '477 certainly would not consider a capacitor in the circuit to be a "power source".

In addition, Susset et al '477 does not show, disclose or suggest the coil be "centrally located and substantially carried on the housing proximal face"; on the contrary, Susset et al '477 specifically teaches away from the coil being centrally located and carried on the housing proximal face by depicting and describing the coil being distinctly separated from the implantable medical device (Figure 1, and throughout the specification).

By contrast, claims 1, 21 and 22 require "a rechargeable power source carried in the housing interior cavity and electrically coupled to the electronics" (claim 1, lines 7 and 8; claim 21, lines 7 and 8; claim 22, lines 7 and 8), and "a recharging coil centrally located and substantially carried on the housing proximal face" (claim 1, lines 9 and 10; similar requirement in claim 21, lines 11 – 12). As described above, not only does Susset et al '477 not show, disclose or suggest the use of either of these elements, Susset et al '477 specifically teaches away from using them by declaring outright that there is no internal power supply, and by showing the coil physically highly separated from the implantable device.

Susset et al '477 does not show, disclose or suggest the existence of an internal power source, nor a coil centrally located and carried on a proximal face of a housing. Thus, it is respectfully submitted that the rejection of claims 1, 21 and 22 under 35 U.S.C. § 102(b) in view of Susset et al '477 is improper and should be withdrawn.

Claims 2-7, 9, 14, 16 and 20 are dependent on claim 1, and are thus subject to all of the limitations of claim 1. Because the rejection of claim 1 is improper, it is respectfully submitted that the rejection of claims 2 – 7, 9, 14, 16 and 20 are also inappropriate and should be withdrawn.

Rejections under 35 U.S.C. § 103

Claims 10 and 13 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Susset et al '477 as applied to claims 9 and 14 above, and further in view of Fischell '260. These rejections are respectfully traversed.

Claims 10 and 13 are dependent on claim 1, and thus incorporate all of the limitations of claim 1, and, as discussed above, neither Susset et al '477 nor Fischell '260 show, disclose or suggest all of the elements of claim 1. Thus, it is respectfully submitted that Susset et al '477 and Fischell '260 cannot show, disclose or suggest all of the elements of dependent claims 10 and 13, and thus the rejection of claims 10 and 13 under 35 U.S.C. § 103(a) is improper and should be withdrawn.

Claims 12 and 13 have been rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Fagan '129 as applied to claim 1. These rejections are respectfully traversed.

Claims 12 and 13 are dependent on claim 1, and are subject to all of the limitations of claim 1. Because Fagan '129 does not disclose all of the elements of claim 1, as described above, claims 12 and 13 cannot be obvious in view of Fagan '129. Thus, it is respectfully submitted that the rejection of claims 12 and 13 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Fagan '129 is improper and should be withdrawn.

Claims 12 and 13 have been rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Leysieffer '677 as applied to claim 1. These rejections are respectfully traversed.

Claims 12 and 13 are dependent on claim 1, and are subject to all of the limitations of claim 1. Because Leysieffer '677 does not disclose all of the elements of claim 1, as described above, claims 12 and 13 cannot be obvious in view of Fagan '129. Thus, it is respectfully submitted that the rejection of claims 12 and 13 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Leysieffer '677 is improper and should be withdrawn.

Summary

In view of the arguments presented, claims 1 – 22 should be allowable, this application should be in condition for allowance and a notice to that is earnestly solicited.

Respectfully Submitted,

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